

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC.,	:	
	:	
Plaintiff/Counterclaim	:	
Defendant,	:	
	:	
v.	:	Civil Action No. 02-212 JJF
	:	
DIGENE CORPORATION,	:	
	:	
Defendant/Counterclaim	:	
Plaintiff,	:	
	:	
v.	:	
	:	
ENZO BIOCHEM, INC.,	:	
	:	
Additional Counterclaim	:	
Defendant/Declaratory	:	
Plaintiff.	:	

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Attorneys for Defendant/Counterclaim Plaintiff Digene Corporation.

MEMORANDUM OPINION

February 19, 2004

Wilmington, Delaware

Farnan, District Judge.

Presently before the Court are two motions, Digene Corporation's ("Digene") Motion For Partial Summary Judgment Of Invalidity For Lack Of Written Description (D.I. 78) and Plaintiff Enzo Life Sciences, Inc.'s ("Life Sciences") Cross-Motion For Partial Summary Judgment That The Claims Of The '581 Patent Are Not Invalid For Lack Of Written Description. (D.I. 100.) For the reasons discussed, the Court will deny both motions.

BACKGROUND

This case is a patent infringement action brought by Life Sciences against Digene for alleged infringement of Life Sciences's U.S. Patent No. 6,221,581 (the "'581 patent"). Life Sciences alleges that Digene's products infringe on claims 19-26, 30-40, 44-53, 73-87, 91-100, and 104-07 of the '581 patent. By its Motion, Digene requests the Court to find, as a matter of law, that claims 3, 4, 16, 18, 19, 32, 33, 44, 46, 60, 61, 75, 76, 91, 93, 94, 110, 111, 112, 123, 128, and 131 are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, paragraph one. By its Cross-Motion, Life Sciences requests the Court to find, as a matter of law, that the claims of the '581 patent are not invalid for lack of written description.

STANDARD OF REVIEW

Rule 56(c) of the Federal Rules of Civil Procedure provides that a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a triable dispute of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000). Thus, to properly consider all of the evidence without making credibility determinations or weighing the evidence the "court should give credence to the evidence favoring the [non-movant] as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.'" Id. (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254 (1986)).

To defeat a motion for summary judgment, Rule 56(c) requires the non-moving party to:

do more than simply show that there is some metaphysical doubt as to the material facts. . . . In the language of the Rule, the non-moving party must come forward with "specific facts showing that there is a genuine issue for trial." . . . Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is "no genuine issue for trial."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986) (quoting Fed. R. Civ. P. 56). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. Liberty Lobby, Inc., 477 U.S. at 252 (1986).

I. Digene's Motion For Partial Summary Judgment (D.I. 78)

A. Contentions

Digene contends that multiple claims in the '581 patent are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. Digene contends that all of the claims it has identified contain the terms "capturing domain" and "signaling domain" (the "claim terms") which have no plain or ordinary meaning in the relevant art and are not defined in the written description of the '581 patent. In addition, Digene contends that the inventors of the '581 patent have conceded that the claim terms are identifiable only by their biological function. Thus, Digene contends that under applicable law, particularly Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), the claims at issue are invalid. Further, Digene contends that Life Sciences's

submission of an expert declaration does not create a genuine issue of fact because it consists only of conclusory statements unsupported by facts.

Life Sciences responds that Digene's Motion should be denied because its arguments relate to issues of claim construction and not lack of written description. Life Sciences also contends that the question of whether a patentee has complied with the written description requirement is a question of fact, and that Digene has failed to present any evidence that one of ordinary skill in the art would not know that the inventors were in possession of the invention they claimed. Further, Life Sciences contends that functional language, like that used in the '581 patent, is permissible under settled Federal Circuit precedent, and, moreover, that the issue of functional claiming does not arise in this case because Life Sciences has not attempted to claim a specific genus or genetic sequence.

B. Discussion

Whether a patent complies with the written description requirement is an issue of fact. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003). The burden of establishing that a patent fails the written description requirement rests with the challenging party. Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574-75 (Fed. Cir. 1992). And, as issued patents carry a presumption of validity, a

challenger can demonstrate invalidity only by clear and convincing evidence. WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1354 (Fed. Cir. 1999).

The written description requirement of Section 112 requires an applicant to give a description that clearly allows persons of ordinary skill in the art to realize that he or she invented what is claimed. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). According to the Federal Circuit, this requirement is satisfied when an applicant demonstrates that he or she is "in possession" of the invention claimed. Lockwood v. Am. Airlines, 107 F.3d 1565, 1572 (Fed. Cir. 1997). To show that one is "in possession," an applicant must describe the invention, with all its claimed limitations, and not only what makes it obvious. Id. "[The] specification must contain an equivalent description of the claimed subject matter," id.; however, the "'application need not describe the claimed subject matter in exactly the same terms as used in the claims.'" Id. (quoting Eiselstein v. Frank, 52 F.3d 1035, 1038 (Fed. Cir. 1995)). Applying these standards to the arguments advanced by Digene, the Court will deny Digene's Motion.

Digene's contentions regarding lack of written description focus on three primary issues: 1) the lack of any ordinary meaning of the claim terms at issue to one skilled in the art; 2) the absence of any definition of the claim terms in the

specification of the '581 patent; and 3) the use of functional language to define the claim terms which are "at the point of novelty." Beginning with Digene's first contention regarding lack of written description, the Court concludes that the lack of an ordinary meaning in molecular biology of the claim terms is insufficient to establish lack of written description. The proper inquiry in determining whether the requirements of Section 112, paragraph one, are met is not whether the claim terms have an ordinary meaning to one of skill in the art; rather, the key is whether the specification sufficiently apprises one of ordinary skill in the art that the applicant has invented what they claim. All Dental Prodx, LLC & DMG v. Advantage Dental Prods., 309 F.3d 774,799 (Fed. Cir. 2002).

The Court must also reject Digene's contention that the absence of a definition of the claim terms in the specification establishes a failure to satisfy the written description requirement. (D.I. 81 at 6.) Digene's argument concerning lack of definition is based upon the absence of the claim terms in the '581 patent's specification. (D.I. 81 at 6-7.) However, as noted above, the specification of a patent need not include language used in the claims in order to satisfy the written description requirement, an "equivalent description" is sufficient. See Lockwood, 107 F.3d at 1572; All Dental, 309 F.3d at 799 (quoting Eiselstein v. Frank, 52 F.3d 1035 (Fed. Cir.

1995); Robert L. Harmon, Patents and the Federal Circuit § 5.4(c) (6th ed. 2003). In addition, Life Sciences has proffered evidence that one of ordinary skill in the art would understand the meaning of the claim terms upon reading the specification. (D.I. 103 at 4-5.) Based on this evidence, the Court concludes that a genuine issue of fact exists over whether one skilled in the art could determine the meaning of the claim terms from reading the disclosure of the '581 patent, and therefore, will deny Digene's summary judgment motion on this issue.

With respect to Digene's last argument concerning lack of written description, the Court concludes that a material dispute of fact exists over whether use of the allegedly functional claim terms satisfies the written description requirement. Digene contends that the use of functional language in the '581 patent only describes what the invention does, rather than what it is, thereby running afoul of the prohibitions set forth in Regents of the Univ. of California v. Eli Lilly & Co. However, the Court does not understand recent Federal Circuit precedent interpreting Eli Lilly to prohibit the use of functional language in the instant case. The Federal Circuit in Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316 (Fed. Cir. 2002), stated that it is only when the use of functional language fails to adequately describe the invention to one of ordinary skill in the art that the language runs afoul of the written description requirement.

Id. at 1326-27.

Life Sciences offers the declaration of one allegedly skilled in the art, Dr. Wetmer (D.I. 103), in support of its contention that the specification adequately discloses the invention at issue. In his declaration, Dr. Wetmer states that the claim terms would be adequately understood by a skilled artisan based on the plain language of the claims of the '581 patent. Id. at 4. Dr. Wetmer also directs the Court to various sections of the specification, indicating that one skilled in the art "would immediately recognize that the inventions claimed in the '581 patent are fully described by the specification of that patent." Id. at 4-5. Based on this evidence, the Court concludes that Digene has not established that it is entitled to summary judgment. The question of whether the specification makes disclosures to one of ordinary skill in the art sufficient to satisfy the written description requirement is an issue of disputed fact, and therefore, improper for resolution by summary judgment.

II. Life Sciences's Cross-Motion (D.I. 100)

By its Cross-Motion, Life Sciences moves for summary judgment that the claims of the '581 patent are not invalid for lack of written description. For the reasons set forth below, the Court will deny Life Sciences's Cross-Motion.

A. Contentions

Life Sciences contends that because Digene has not come forward with evidence of whether the specification would apprise one skilled in the art that the inventors of the '581 patent were in possession of the invention, it is entitled to a finding, as a matter of law, that the claims of the '581 patent are not invalid for lack of written description. Life Sciences contends that it is entitled to judgment on all of Digene's Section 112 defenses because Digene did not provide evidence supporting these defenses in its opposition to Life Sciences's Cross-Motion.

Digene responds that the only issue appropriate for the Court to resolve is whether use of the claim terms satisfies the written description requirement. Digene contends that this was the only issue discussed in Life Sciences's opening brief in support of its Cross-Motion even though Life Sciences titled its cross-motion as moving for judgment on all issues related to written description. Thus, Digene contends that it would be improper for the Court to resolve questions related to the issues of new matter, priority, and its other Section 112 defenses at this time.

B. Discussion

After reviewing the papers submitted by the parties, the Court agrees with Digene that it would be inappropriate at this juncture to resolve invalidity questions not at issue in Digene's

motion for summary judgment. A review of Life Sciences's opening brief in support of its Cross-Motion reveals that it only discusses the issues raised in Digene's motion for summary judgment and not Digene's remaining Section 112 invalidity defenses. (D.I. 101 at 21.) Therefore, the Court cannot fault Digene for failing to adequately respond to these issues.¹

CONCLUSION

For the reasons discussed, the Court will deny Digene's Motion For Partial Summary Judgment Of Invalidity For Lack Of Written Description (D.I. 78) and Life Sciences's Cross-Motion For Partial Summary Judgment That The Claims Of The '581 Patent Are Not Invalid For Lack Of Written Description. (D.I. 100.)

An appropriate Order will be entered.

¹ Of course, the Court must also deny Life Sciences's Cross-Motion for summary judgment relating to issues raised in Digene's summary judgment motion. As previously discussed, the Court concludes that disputed issues of material fact preclude the entry of judgment on these issues.

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Additional Counterclaim	:	
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ORDER

At Wilmington, this 19th day of February, 2004, for the
reasons discussed in the Memorandum Opinion issued this date;

NOW THEREFORE, IT IS HEREBY ORDERED that:

- 1) Digene Corporation's Motion For Partial Summary
Judgment Of Invalidity For Lack Of Written Description
(D.I. 78) is **DENIED**;
- 2) Enzo Life Sciences's Cross-Motion For Partial Summary
Judgment That The Claims Of The '581 Patent Are Not
Invalid For Lack Of Written Description (D.I. 100) is
DENIED.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE